

03/14/02

#1513

RECEIVED

MAR 11 2002

TECH CENT 600/2900

HO-P01899US2 (PATENT)

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as Express Mail, Airbill No. EU098494585US, in an envelope addressed to: Commissioner for Patents, Washington, DC 20231, on the date shown below.

Dated: March 11, 2002

Signature: *Susan Hunter*
Susan Hunter

Docket No.: HO-P01899US2
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Patent Application of:
Huda Y. Zoghbi et al.

Customer No. 26271
(09906355 / OTA 99-47 / LVM 205429)

Application No.: 09/585,645

Group Art Unit: 1633

Filed: June 1, 2000

Examiner: Not Yet Assigned

For: COMPOSITIONS AND METHODS FOR THE
THERAPEUTIC USE OF AN ATONAL-
ASSOCIATED SEQUENCE FOR DEAFNESS,
OSTEOARTHRITIS AND ABNORMAL CELL
PROLIFERATION

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action mailed January 15, 2002 (Paper No. 13). A Petition for One Month Extension of Time is submitted herewith, including the requisite fee.

Claims 40-50 and 112-123 are currently pending in the application. Applicants note the error by the Examiner on the Office Action Summary page wherein claim 112 was failed to be cited as pending. However, this mistake is not carried through in the Detailed Action, and Applicants confirm herein that claim 112 is pending in the application.

In the Response filed October 10, 2001 for the Office Action mailed September 14, 2001, Applicants elected Group IV of the restriction, with traverse, directed to the pending claims 40-50 and 112-123 regarding a method of generating hair cells and a composition comprising *atonal*-associated nucleic acid sequence.

In the Office Action mailed January 15, 2002, the Examiner further requires restriction between new Groups I, II, and III. Thus, the Examiner alleges that claims 40-45,

48, 112-115 and 123 are deemed generic.

The Examiner has required an additional restriction between:

Group I. Claims 46, 47, 50, 116, 117, 118, 119 and 121, drawn to a method of generating hair cell by delivering an atonal-associated nucleic acid sequence, and a composition comprising atonal-associated nucleic acid sequence.

Group II. Claims 49 and 120, drawn to a method of generating hair cell by delivering an atonal-associated amino acid sequence, and a fusion protein comprising an atonal-associated amino acid sequence and a desired amino acid sequence.

Group III. Claim 122, drawn to a method of generating hair cell by delivering an atonal-associated nucleic acid sequence and a second nucleic acid sequence encoding a non-atonal-associated therapeutic agent.

Applicants hereby provisionally elect Group I having claims 46, 47, 50, 116, 117, 118, 119, and 121 for continued examination, with traverse.

The Commissioner may require restriction if two or more independent and distinct inventions are claimed in a single application (37 CFR 1.142(a)). In the present case, although the claimed subject matter may be classified in different classes, Applicants assert that the inventions are not independent. Applicants propose that the claims of Group I should be examined with the claims of Group III, because references cited by the Patent Office against Group III will almost certainly be cited against the claims of Group I. Accordingly, there can be no undue burden on the Examiner in examining the claims of Group III with the claims of elected Group I. As stated in MPEP §803, there are two criteria for a proper requirement for restriction between two patentably distinct inventions: 1) the inventions must be independent or distinct as claimed ; **AND** there must be a serious burden on the examiner if restriction is required (emphasis added).

It is respectfully requested that the restriction requirement be withdrawn, and that each of claims 46, 47, 50, 116, 117, 118, 119, 121 and 122 presently pending in this application be examined.

Applicants believe that no other fees are due. However, if fees are deficient now or at any time during the prosecution of this application, please charge them to the standing account of Fulbright & Jaworski L.L.P., 06-2375, under Order No. 09906355.

Dated: March 11, 2002

Respectfully submitted,

By Melissa L. Sistrunk
Melissa L. Sistrunk

Registration No.: 45,579
FULBRIGHT & JAWORSKI L.L.P.
1301 McKinney, Suite 5100
Houston, Texas 77010-3095
(713) 651-5151
(713) 651-5246 (Fax)
Agent for Applicants